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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,376	05/30/2001	Jeffrey P. Bodner	279.368US1	7232

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/870,376	Applicant(s) BODNER, JEFFREY P.	
	Examiner Frances P. Oropeza	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/17/06 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response

1. In the response filed 3/17/06 the Applicant amended the independent claims, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claims 1-7, 9-13, 15-20, 22, 24-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Cobain et al. (US 5796044). Cobain et al. teach a lead assembly with two co-axial and non co-radial single filar or multi-filar conductors. The second conductor is disposed within the first conductor, and the first and second second conductors may have an insulative coating disposed directly thereon surrounding the outer filar surface such that a cross-section of the outer filar surface is surrounded by the insulative coating, the coating being a polyurethane (abstract; col. 2 @ 36-40; col. 4 @ 7-23; col. 5 @ 12-60; col. 7 @ 58-67; col. 9 @ 66 –col. 10 @ 14). All leads have a flexibility, the disclosed lead has flexibility enabling placement in the heart (col. 8 @ 1-6).

As to claims 3, 4, 6, 13 and 17, an insulative sleeve (38)/ tube/ redundant insulation is disposed between the first and second conductor, the sleeve made of polyethylene (fig. 9; col. 4 @ 11-15; col. 11 @ 4-6). The internal sheath (27) is noted to be optional (col. 8 @ 44-47).

As to claims 5, 10, 15, 16, 22 and 26, the sleeve/ coating can be made of a non-silicon polymer such as polyurethane, ETFE, PTFE, and PFA (col. 5 @ 57-67; col. 12 @ 42-50).

As to claims 9, 13, 17, 20, 28 and 29, the first conductor is insulated (22) (fig. 9; col. 11 @ 4-9).

As to claims 11, 18 and, 25, an extendable/ retractable electrode is taught (col. 8 @ 1-14).

As to claim 30, when the insulative sleeve (38) is formed by coating or extrusion, the sleeve forms a tight intimate bond with the second conductor, hence the tubular insulative sleeve rotates relative to the first conductor (col. 4 @ 7-15; col. 5 @ 12-60; col. 11 @ 4-6).

3. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Helland et al. (US 5545201). As discussed in paragraph 2 of this action, Cobain et al. disclose the claimed invention except for a means for facilitating rotation of the second conductor relative to the first conductor.

Helland et al. teach an electrode configuration using an electrode assembly with an extendable/ retractable electrode (144) coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug (176) for the purpose of fixing/ securing the electrode to the heart wall. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an extendable/ retractable electrode coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug in the Cobain et al. system in order to accurately sense and stimulate the heart so there is accurate discrimination of the cardiac rhythm enabling effective therapy to be offered to the patient (figure 6; col. 1 @ 6-11 and 48-58; col. 1 @ 62 – col. 2 @ 5; col. 4 @ 56 – col. 5 @ 15).

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4. Claim 21, 23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Altman et al. (US 5845396). As discussed in paragraph 2 of this action, Cobain et al. disclose the claimed invention except for the insulation / coating being a polyimide material.

Altman et al. teach signal conduction using a lead with polyimide coated conductors for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart are accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

5. Claims 23, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Nelson et al. (US 6249708). As discussed in paragraph 2 of this action, Cobain et al. teach applying various Teflon™ materials such as PTFE and ETFE on the second outer coil diameter and over the insulation (col. 5 @ 57-67; col. 12 @ 42-50), but do not teach applying heat shrunken Teflon™ material on the second outer coil diameter and insulation (claims 23 and 27).

Nelson et al. teach lead construction using heat-shrunken Teflon™ (38) for the purpose of insulating the central core conductor (34). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunken Teflon™ PTFE or ETFE to on the second outer coil diameter and insulation in the Cobain et al. system in order to reinforce the assembly and provide a proven alternate approach of applying Teflon

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™ to the second outer coil diameter and insulation, hence adding flexibility in the lead manufacturing process (col. 4 @ 27-45; col. 7 @ 46-48).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3766

FPO
4/12/06


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766